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Roxane Laboratories, Inc.

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October 26, 1999

PROPOSED RULE PUBLIC HEARING (DOCKET NO. 98N-0617)

Ann Maloney
Telephone 614-241-4130
Telefax 614-276-0321
E-Mail

P.O. Box 16532
Columbus, Ohio 43216-6532
Telephone (614) 276-4000

Dear Sir or Madam:

Attached is a written notice of participation in response to the Notice of Public Hearing (Docket No. 98N-0617) which will be held on November 1, 1999.

If you have any questions, please do not hesitate to contact Ann Maloney at (614) 241-4130 or by telefax at (614) 276-0321.

Best regards.

Betty Payne
Coordinator - DRA-Approved Products

98N-0617

APE-3



Boehringer Ingelheim
Roxane Laboratories

Center for Substance
Abuse Treatment (CSAT)
Office of Pharmacological
and Alternative Therapies
5515 Security Lane
Rockwall II
Rockville, MD 20857

Roxane Laboratories, Inc.

**Re: Proposed Rule Public Hearing
Docket No. 98N-0617**

Dear Sir or Madam:

October 26, 1999

Roxane Laboratories, Inc. is submitting a written notice of participation in response to the Notice of Public Hearing (Docket No. 98N-0617) which will be held on November 1, 1999.

Sidney S. Schnoll, M.D., Ph.D. and Richard Rawson, Ph.D. will be presenting information on behalf of Roxane Laboratories. Please allow twenty minutes for each presentation. Due to scheduling conflicts with one of our presenters on the West Coast, we request that we be allowed to give our presentations early (preferably in the A.M.) on November 1, 1999.

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Dr. Schnoll will speak on the following subjects during his 20-minute presentation:

- the need for addiction to be treated like other chronic diseases i.e., hypertension, diabetes
- allowing the flexibility to use clinical judgement based on the physician-patient relationship to determine the best approach for the patient, coupled with more treatment medication options
- removing the prohibition of take-home LAAM
 - discussion of the four options presented in the proposed regulations

During Dr. Rawson's 20-minute presentation, he will present study results on a feasibility study of take-home LAAM in the treatment of opiate dependence. The overall objective of the study was to evaluate the therapeutic benefits and feasibility of "Take-Home" LAAM (i.e., LAAM administered under the supervision of health care professionals, but taken by the subject at home or in a nonclinical setting). The primary objective



of the study was to compare the clinical response (efficacy and safety) of subjects who received "Take-Home" LAAM privileges with that of subjects receiving LAAM without "Take-Home" privileges. The secondary objective of the study was to determine if subjects who received "Take-Home" LAAM attempted diversion of the medication when it was used with a random recall procedure and other diversion safeguards, and the possible correlations between treatment response for subjects assigned to either treatment group. Variables such as background and demographic drug use at intake, during treatment, or at discharge were also examined.

Below is a list of Roxane's participants and presenters including their appropriate business affiliations:

Roxane Participants:

Ann Maloney	Director, Drug Regulatory Affairs - Approved Products
Ann Kline	Clinical Research Manager, Medical Affairs
Jerry Sincich	Director, Addiction Treatment
Raymond Chlebicki	National Sales Manager - Specialty Sales

Presenters:

Richard Rawson, Ph.D. (Consultant to Roxane Laboratories, Inc.)
Executive Director
Matrix Institute on Addictions
10350 Santa Monica Blvd.
Suite 330
Los Angeles, CA 90025
Ph: 310-785-9666
Fax: 310-785-9165

Sidney H. Schnoll, M.D., Ph.D. (Consultant to Roxane Laboratories, Inc.)
Chairman, Division of Addiction Medicine
Medicinal College of Virginia Hospitals
1200 East Broad Street
West Hospital, 11th Floor
P.O. Box 98109
Richmond, VA 23298-0109
Ph: 804-828-9914
Fax: 804-828-9906

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Should you have any questions or comments, please do not hesitate to contact me at (614) 241-4130 or by telefax at (614) 276-0321.

Sincerely,

A handwritten signature in cursive script that reads "Ann M. Maloney".

Ann M. Maloney
Director, Drug Regulatory Affairs – Approved Products